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Summary of Safety and Effectiveness

NOV 9 2012

Date: September 5, 2012

U.S. Contact Person:
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Principal Consultant
Phone: 574-527-4220

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

Product	Product Code	Regulation and Classification Name
H-Max S femoral hip system	MEH	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
	JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350

Description:

The H-MAX S femoral system consists of the H-MAX S femoral stem, a femoral head and an acetabular cup. The H-Max S Stems are intended for use with CoCrMo femoral heads and Limacorporate Cemented cups.

The **H-MAX S femoral stem** is a monolithic cementless stem made from Ti6Al4V (ISO 5832-3, ASTM F1472). The external surface has a macro-roughened surface. A layer of hydroxyapatite is applied along the length of the stem. The H-MAX S stem is manufactured in 11 sizes for each of two configurations (standard and lateralizing) that vary in the CCD angle.

Intended Use:

The H-Max S stems are indicated for use in total hip arthroplasty and are intended for press-fit (uncemented) use. The H-Max S Stems are intended for use with Co-Cr-Mo femoral heads and Limacorporate standard and protruded cemented cups. The standard and protruded cemented cups are intended for cemented use only.

Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

Traditional 510(k) – H-MAX S femoral hip system

Predicate Devices:
Corail AMT Femoral stem (Depuy, K042992)

Comparable Features to Predicate Device(s): the H-MAX S femoral hip system is similar to the predicate devices in terms of intended use, indications, design and materials.

The H-Max S stem and the Corail AMT stem are both indicated for use in total hip arthroplasty for press-fit (uncemented) use. Like the Corail AMT hip prosthesis, the H-MAX S femoral stem is a monolithic stem with a wide medial curvature and an A-P profile characterized by the "V" shape in the proximal part. Both prostheses are characterized by a 12/14 neck-head taper and the surface has a layer of Hydroxyapatite.
The components of the H-MAX S femoral hip system are manufactured from the same materials as the predicate devices.

Non-Clinical Testing: The H-MAX S femoral hip system has undergone fatigue testing to demonstrate the strength of the femoral stem and the femoral neck. Pull-off testing to demonstrate the strength of the taper connection between the femoral stem and the modular CoCrMo heads has also been completed. A simulation of the Range of Motion has been performed to ensure the device design does not overly limit range of motion.
All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the system's ability to perform under expected clinical conditions.
The Hydroxyapatite coating has been characterized according to the FDA guidance documents.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the H-MAX S femoral hip system to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 9, 2012

Limacorporate SPA
% Hastings Regulatory Consulting, LLC
Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590-696

Re: K112091
Trade/Device Name: H-MAX S femoral hip system
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, JDI
Dated: September 05, 2012
Received: October 01, 2012

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K112091

Device Name: H-MAX S femoral hip system

Indications for Use:

H-MAX S femoral hip system
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112091

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